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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,494	07/25/2001	Robert Thomas Hudak	AC-00127.P.1	6752

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EXAMINER

COUNTS, GARY W

ART UNIT PAPER NUMBER

1641

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/915,494	Applicant(s) HUDAK, ROBERT THOMAS	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/04 & 5/10/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The amendment filed March 22, 2004 is acknowledged and has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1, part (b) the recitation "reservoir is receives" should be --reservoir receives--.

Claim 23 is objected to because of the following informalities. Claim 23 is considered a duplicate of claim 1. Amended claim 1 now recites that said valve can be actuated only once. Therefore, claim 23 fails to further limit claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, part (b) the recitation "capable of" is vague and indefinite. The recitation is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim 1, part (c) the recitation "can be" is vague and indefinite. The recitation is not a positive limitation.

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Claims 35 and 37-39 the recitation "capable of" is vague and indefinite. The recitation is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. These claims were rejected in the previous office action along with claim 1 (see previous office action).

Claim 48 the recitation "can be" is vague and indefinite. The recitation is not a positive limitation. Is a temperature sensing device examined or not? And if so, it is unclear what relationship exists between this examination and detecting the analyte.

Claim 60, line 2 "functionally disengages" is vague and indefinite. It is unclear what applicant intends. Does the handle physically separate from the valve? Does the handle somehow change conformation or position, which causes valve to be disengaged? Please clarify.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 13, 15, 16, 17, 19, 20, 22, 26, 27, 29, 31, 33-39, 42, 44-46, 49 and 51-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Cui et al (US 6,576,193).

Cui et al disclose devices and methods for collecting a fluid specimen and testing the fluid specimen for detecting the presence of a particular analyte. Cui et al disclose a first compartment (chamber) for fluid collection. Cui et al disclose a second compartment (reservoir) for receiving a portion of the fluid. Cui et al disclose a valve interposed between the first compartment and the second compartment (Fig. 1 and Fig. 9). Cui et al disclose that the first compartment (chamber) comprises a lid for sealing the fluid within the first compartment (col. 4, lines 1-9). Cui et al disclose that the second compartment is spaced to allow receipt of a test device such as a test strip (col 5). Cui et al disclose that test strips using immunoassays or chemical patches can be used to determine an analyte of interest (col 7, lines 37-60). Cui et al disclose that the fluid sample can be blood, plasma, serum or urine (col. 7, lines 1-20).

5. Claims 1, 11, 14, 16, 17, 19, 20, 22, 30, 32-46, 49, and 51-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Hudak et al (US 6,565,808).

Hudak et al disclose a sample receiving chamber and a test platform (reservoir). Hudak et al disclose a valve functionally interposed between the chamber and test platform (reservoir) (Fig. 1, item 20).

6. Claims 1-4, 11, 14, 16, 17, 19, 21-23, 28, 29, 31, 33, 34, 39, 40, 44-47, 49, and 51-54 rejected under 35 U.S.C. 102(e) as being anticipated by Guirguis et al (US 6,277,646).

Guirguis et al disclose a device and method for determining an analyte of interest. Guirguis et al disclose a collection chamber, isolating chamber and a testing chamber (reservoir) which comprises a test strip. Guirguis et al disclose a fluid releasing element

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(valve) interposed between the collection chamber, isolation chamber and test chamber (reservoir). Guirguis et al disclose that the fluid releasing element (valve) opens the isolation chamber and releases fluid from the isolating chamber allowing fluid to be directed to the test chamber (reservoir) (col 7).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 3, 5, 7, 8, 18, 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Nelson et al (US 5,115,934).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the seal is tamper resistant.

Nelson et al disclose a tamper resistant seal for containers. Nelson et al disclose that this tamper resistant seal provides for a cover that is secure but yet may be easily removed providing access to the container.

It would have been obvious to one of ordinary skill in the art to incorporate a tamper resistant seal as taught by Nelson et al into the device and method of Cui et al because Nelson et al shows that this tamper resistant seal provides for a cover that is secure but yet may be easily removed providing access to the container.

With respect to the specimen volume as recited in the instant claims, the optimum specimen volume can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation.” Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation .” Id. At 458,105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Alley (US 2002/00446614).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the seal comprises at least one O-ring.

Alley discloses a seal comprising an O-ring. Alley discloses that the use of this O-ring provides a means of securing the seal to the container. Furthermore, the use of O-rings in a seal is well known in the art.

It would have been obvious to one of ordinary skill in the art to incorporate an O-ring as taught by Alley into the device of Cui et al because Alley shows that the use of this O-ring provides a means of securing the seal to the container.

11. Claims 9, 32, 43, 48 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Ehrenkranz (US 4,769,215).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the chamber comprises a temperature-sensing device.

Ehrenkranz discloses a urine collection apparatus, which comprises a thermometer within the device. Ehrenkranz discloses that the use of this thermometer provides a means for determining the freshness of the urine and also provides an alternative for physical examination (col. 5, lines 19-37 and abstract).

It would have been obvious to one of ordinary skill in the art to incorporate the thermometer as taught by Ehrenkranz into the device of Cui et al because Ehrenkranz shows that the use of this thermometer provides a means for determining the freshness of urine and also provides an alternative for physical examination.

With respect to the recitation "wherein said reservoir is removable from said chamber" as recited in the instant claims. Cui et al disclose the claimed invention except for teaching the reservoir is removable from the chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the chamber and reservoir as separate parts, since it has been held that constructing a formerly intergral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

12. Claim 10-12, 14, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Kantner (US 4,211,749).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the chamber comprises a label on which to record data pertaining to the specimen. Cui et al also fails to teach the chamber is tapered. Cui et al also fails to specifically teach that the container comprises plastic.

Kantner disclose a urine container, which comprises an informative label containing important information relative to the patient in a manner ensuring that the label is not lost. Furthermore, it is well known in the art to place a label on a container to record patient information on the container. Kantner et al also disclose the container is tapered. Kantner disclose that this provides nesting of successive containers on top of one another. Kantner also teach that the container is made of plastic which allows for a successful and cheap material (col. 15, lines 1-14).

It would have been obvious to incorporate a label such as taught by Kantner et al in the device of Cui et al because Kantner shows that the use of such a label provides for important

information relative to the patient in a manner ensuring that the label is not lost. It also would have been obvious to one of ordinary skill in the art to taper the device of Cui et al such as taught by Kantner because Kantner discloses that this provides nesting of successive containers on top of one another. It also would have been obvious to one of ordinary skill in the art to incorporate plastic as taught by Kantner into the device of Cui et al because Kantner teaches that the plastic material allows for successful and cheap material in a urine container.

13. Claims 21, 24, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Mitsumaki et al (US 4,680,270) and Godin et al (US 3,991,055).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the valve comprises a piston configuration. Cui et al also fail to teach that the valve comprises an O-ring.

Mitsumaki et al teaches the equivalence of rotary valves and slide valves in the art.

Godin et al teach a sliding valve which comprises a piston and O-ring for the transfer of liquid sample. Godin et al disclose that the use of such a valve provides for the operator to choose between segmenting operation on a sample or a prediluted sample without using separate valving and considerable increase in fluid lines.

It would have been obvious to one of ordinary skill in the art to incorporate slide valves as taught by Godin et al into the device of Cui et al because Mitsumaki et al shows that it is known in the art to use slide valves instead of rotating valves and because Godin et al shows that the use of such a valve provides for the operator to

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choose between segmenting operation on a sample or a prediluted sample without using separate valving and considerable increase in fluid lines.

14. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guirguis et al in view of Pampinella (US 2002/0023482).

See above for teachings of Guirguis et al.

Guirguis et al differs from the instant invention in failing to teach the valve comprises a handle for actuating the valve, wherein the handle functionally disengages from the valve after the valve is actuated and wherein the valve cannot be actuated with the handle functionally disengaged therefrom.

Pampinella teaches a valve handle which is detachably connected to the valve (page 1, paragraph 0034). Pampinella teaches that the use of this valve facilitates the opening and closing of the valve.

It would have been obvious to one of ordinary skill in the art to incorporate a handle such as taught by Pampinella with the valve of Guirguis et al because Pampinella teaches that the use of this valve facilitates the opening and closing of a valve.

With respect to the recitation “ wherein the valve cannot be actuated with the handle functionally disengaged therefrom” as recited in the instant claims. One of ordinary skill would recognize that when the handle of Pampinella is detached the valve could not be engaged.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-20 and 22-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-62 of copending Application No. 10/211,199. Although the conflicting claims are not identical, they are not patentably distinct from each other because one skilled in the art would recognize that the narrow claims of the device concerning the valve in application 10/211,199 would encompass the more broad claims of the device in application 09/915,494 .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

17. Applicant's arguments filed November 22, 2004 have been fully considered but they are not persuasive.

Applicant argues that Cui et al (US 6,576,193) fails to teach or suggest a valve that can be actuated only once. This is not found persuasive because the recitation "actuated only once" is intended use of the valve and the valve of Cui et al is capable of

being actuated only once. Therefore, Cui et al reads on the instantly recited claims. Further, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues that Guirguis et al (US 6,277,646) fails to teach or suggest a valve that can be actuated only once and that Guirguis does not provide any limit on how many times the releasing element (valve) can be actuated and that in contrast, the valve of claim 1 can only be actuated once. This is not found persuasive because the recitation "actuated only once" is intended use of the valve and the valve of Guirguis et al is capable of being actuated only once. Therefore, Guirguis et al reads on the instantly recited claims. Further, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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Applicant also argues that Hudak et al (US 6,565,808) fails to teach or suggest a valve that can be actuated only once. This is not found persuasive because the recitation "actuated only once" is intended use of the valve and the valve of Hudak et al is capable of being actuated only once. Therefore, Hudak et al reads on the instantly recited claims. Further, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues that Cui et al in view of Nelson (US 5,115,934) fail either alone or in combination to teach or suggest the subject matter of claims 3, 5, 7, 8, 18, 47, and 50. This is not found persuasive because it is the Examiner's position the Cui reads on the claims of which claims 3, 5, 7, 8, 18, 47 and 50 depend. Therefore, it is the Examiner's position that the combination of Cui et al and Nelson et al reads on the instantly rejected claims.

Allowable Subject Matter

18. The following is a statement of reasons for the indication of allowable subject matter: Even though the following limitation is not recited in the claims the following feature would be considered allowable. The allowable feature would be wherein the handle further includes a frangible head which disengages from the valve after the valve

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is actuated and wherein the valve cannot be actuated with the handle disengaged therefrom.

19. The closest prior reference is considered to be Pampinella (US 2002/0023482). See above for teachings of Pampinella. Pampinella fails to teach or suggest the handle further includes a frangible head, which disengages from the valve after the valve is actuated, and wherein the valve cannot be actuated with the handle disengaged therefrom.

Conclusion

20. No claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gary W. Counts
Examiner
Art Unit 1641
May 5, 2004


LONG V. LE
SUPERVISORY PATENT EXAMINER
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05/13/04